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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,602	07/25/2003	William P. Santamore	08396.0004	9738

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EXAMINER	
KAHELIN, MICHAEL WILLIAM	
ART UNIT	PAPER NUMBER
3762	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/626,602	SANTAMORE ET AL.	
	Examiner	Art Unit	
	Michael Kahelin	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/29/2006 has been entered.

Claim Objections

2. Claim 7 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The limitation "myocardial infarct or ischemic" is more broad than "infracted myocardial" (from the parent claim of claim 7).

3. In claim 19, it appears that "right catheter" should read "right ventricular catheter", and should be amended accordingly.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 16 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitation "reduce the likelihood" is missing a basis of comparison, rendering the claim vague (i.e. "reduced compared to what?" is not ascertainable).

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1, 2, 6-9, 12, 16-18 and 20-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Lafontaine (US 6,343,605, hereinafter "Lafontaine").

8. In regards to claims 1 and 7, Lafontaine discloses a target intramural region, delivering a lead with an electrode (Fig. 14 and claim 3), physically modifying the mechanical properties of the region (claim 1), wherein the region is infracted myocardium (col. 12, line 32) and electrical impulses travel through the infracted region (the pulses inherently travel between the two electrode/anchors shown in Fig. 14, which is also through the infracted region).

9. In regards to claim 2, the modified properties inherently include an increase in systolic performance because Lafontaine's invention contracts at the same time as the heart wall, increasing contraction force.

10. In regards to claim 6, the modified properties include substantially no decrease in diastolic performance because Lafontaine's invention relaxes at the same time as the heart wall.

11. In regards to claim 8, the lead includes an electro-active bridge (622) spanning the infarct zone (Fig. 14).

12. In regards to claim 9, the method comprises delivering an arcuately curved lead to in the intramural space (Fig. 14, element 658; and col. 12, line 14).

13. In regards to claim 12, the lead comprises echo features (654 and 622). Examiner is interpreting this interface as an echo feature because any interface of materials with different densities will generate an ultrasound signal.

14. In regards to claims 16 and 17, the lead comprises a distal portion (654) that is substantially atraumatic because it is of a small size that does not puncture the heart and allows the heart to maintain function, and reduces the likelihood of puncturing the epicardium because it is adapted to avoid migration (Fig. 13).

15. In regards to claim 18, the lead comprises a deflectable shaft (622, 658, and 664).

16. In regards to claim 20, the lead provides multiple sites for pacing (654A and B).

17. In regards to claims 21 and 22, the target region further includes a peri-infarct region, in which motion is also limited (Fig. 14, the region immediately surrounding 652).

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

19. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

20. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lafontaine. Lafontaine discloses the essential features of the claimed invention except for explicitly specifying that the lead comprises radiopaque features. Lafontaine does teach of utilizing radiopaque features on the catheter for visualizing a member during the implantation procedure (col. 6, line 23). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Lafontaine's invention by providing the lead with radiopaque features to allow

visualization of the lead element, in addition to the catheter element, during the implantation procedure.

21. Claims 3, 11, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lafontaine in view of McVenes et al. (US 5,489,294, hereinafter "McVenes"). Lafontaine discloses the essential features of the claimed invention except for providing electrical stimulation with a pacemaker, utilizing a guidewire, or utilizing an anti-inflammatory drug-eluting surface. McVenes teaches of providing electrical stimulation to an intramural electrode with a pacemaker (col. 2, line 56) to provide stimulation in synchrony with the heart's natural rhythm, utilizing a guidewire (22) to accurately place the lead in the desired area, and utilizing an anti-inflammatory drug-eluting surface (col. 2, line 26) to avoid inflammation and other morbidities associated with implanting foreign materials. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Lafontaine's invention by providing electrical stimulation to an intramural electrode with a pacemaker to provide stimulation in synchrony with the heart's natural rhythm, utilizing a guidewire to accurately place the lead in the desired area, and utilizing an anti-inflammatory drug-eluting surface to avoid inflammation and other morbidities associated with implanting foreign materials.

22. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lafontaine in view of Zacouto (US 5,305,745, hereinafter "Zacouto"). Lafontaine discloses the essential features of the claimed invention except for providing the stimulation with a cardioverter/defibrillator or a cardiac resynchronization device.

Zacouto teaches of providing an intramural electrode system with a cardioverter/defibrillator or a cardiac resynchronization device (a defibrillator is a cardiac resynchronization device) (col. 28, line 13) to provide stimulation that will inhibit or treat fibrillation or arrhythmia that is potentially life threatening. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Lafontaine's invention by providing an intramural electrode system with a cardioverter/defibrillator or a cardiac resynchronization device to provide stimulation that will inhibit or treat fibrillation or arrhythmia that is potentially life threatening.

23. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lafontaine in view of Altman (RE 37,463, hereinafter "Altman"). Lafontaine discloses the essential features of the claimed invention except for utilizing a stylet to apply the electrode. Altman teaches of utilizing a stylet to apply an intramyocardial electrode to provide the stiffness necessary to push the lead during placement (abstract). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Lafontaine's invention by providing a stylet to provide the stiffness necessary to push the lead during placement.

24. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lafontaine in view of Vidlund et al. (US 6,616,684, hereinafter "Vidlund"). Lafontaine discloses the essential features of the claimed invention except for placing the device in the intermural space of the left ventricle via a right ventricular catheter introduction. Vidlund teaches of providing a heart-splinting device to the left ventricle via right ventricular catheter introduction to avoid potentially fatal clots in the left ventricle and for

easier vascular access to the implantation site. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Lafontaine's invention by providing the device to the left ventricle via right ventricular catheter introduction to avoid potentially fatal clots in the left ventricle and for easier vascular access to the implantation site.

Response to Arguments

25. Applicant's arguments filed 9/29/2006 have been fully considered but they are not persuasive. Applicant argued that Lafontaine fails to disclose an implantable device configured to physically modify the mechanical properties of myocardial tissue by providing localized reinforcement of infracted tissue, or providing an electrical impulse from an electrode that travels through infracted tissue while at the same time modifying the mechanical properties of that tissue and limits motion in the infarct region. However, referring to Figure 14 of Lafontaine's disclosure, the tendril (622) contracts when electrodes (654A; 654B; col. 13, line 7; and claim 3) are activated. This contracting tendril physically modifies the infracted region (652) by "pulling" on both sides of the region. Further, Lafontaine provides an electrical impulse from an electrode (654A and B) that travels through infracted tissue (because the infracted tissue is between the two electrodes) while at the same time modifying the mechanical properties of that tissue and limits motion in the infarct region (because the tendril (622) is "pulling" on the region, as indicated above, and is localized to the infarct region).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MWK
1/29/07

GEORGE R. EVANISKO
PRIMARY EXAMINER
1/29/7